Appl. No. 10/562,374 March 10, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of: Calvin B. Harley et al.,

Art Unit: 1623

Serial No.: 10/562,374

Filing Date: Dec. 23, 2005

Examiner: Elli Peselev

Confirmation No. 7952

For: COMPOSITIONS AND METHODS FOR INCREASING TELOMERASE

ACTIVITY

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT DETERMINATION

MAIL STOP ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir

Pursuant to 37 C.F.R. § 1.705(b), Applicants respectfully request reconsideration of the patent term adjustment (PTA) determination accorded the above referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 367 days to 447 days is respectfully requested. This request is accompanied by the fee set forth in 1.18(e) and a statement of facts as required under 37 C.F.R. § 1.705(b).

Statement of Facts

Correct PTA and Bases under §§ 1.702, 1.703 and 1.704 for the Adjustment

The correct PTA is **447 days** and not 367 days as stated on the Determination of Patent Term Adjustment under 35 U.S.C. § 1.54(b).

The period of adjustment under 37 C.F.R. § 1.702(a) is 367 days (the "A" delay).

The period of adjustment under 37 C.F.R. § 1.702(b) is to be determined when the instant application issues. The effective period of adjustment as of the mailing date of the Notice of Allowance under 37 C.F.R. § 1.702(b) is **564 days** (the "B" delay).

The period of overlapping days over the period of adjustments under 37 C.F.R. §§ 1.703(a)-(e) is 139 days.

The period of adjustment under 37 C.F.R. § 1.704(a) is 345 days. ("Applicants delay").

The total period of adjustment is [(367+564)-139] - 345 = 447 days.

The relevant dates as specified in 37 C.F.R. §§ 1.703(a)-(e) and the adjustment specified in 37 C.F.R. § 1.703(f)

1. 37 C.F.R. § 1.702(a)

Applicants are in agreement with the USPTO determination of a period of adjustment of 367 days under 37 C.F.R. § 1.702(a). (See Exhibit A attached hereto).

Applicants respectfully request an additional period of adjustment equal to the number of days, if any, in the period beginning on the day after the date that is four months after the date the issue fee is paid and all outstanding requirements were satisfied and ending on the date the patent issues. See 37 C.F.R. § 1.703(a)(6).

2. 37 C.F.R. § 1.702(b)

The period of adjustment under 37 C.F.R. § 1.702(b) begins on the day after the date that is three years from the filing date of the instant application and ends on the day the patent is issued.

In addition to and independent of the "overlap" issue of *Wyeth v. Kappos*, Applicant respectfully submits that for purposes of calculating "B delay", the relevant statutes and regulations require that when calculating "B delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application (i.e., <u>not</u> from the date on which the application fulfilled the requirements of 35 U.S.C. § 371).

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the "actual filing date" of the application.

(B) GUARRANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.

– Subject to the limitations under paragraph (2), it the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the <u>actual filing date</u> of the application in the United States...the term of the patent shall be extended 1 day

for each day after the end of that 3-year period until the patent is issued. 35 U.S.C. 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term "actual filing date" as used in 35 U.S.C. 154(b)(1)(B). PTO delay for a national stage application begins if the Office fails to issue a patent within three years after the date the national stage "commenced under 35 U.S.C. 371(b) or (f).¹

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences"

Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22(1) or (2) or under article 39 (1)(a) of the treaty. 35 U.S.C. §§ 371(b) (emphasis added)

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371 (b), i.e. with the expiration of the applicable time limit under article 22(1) or (2) or under 39(1)(a) of the treaty. The term "treaty" refers to the "Patent Cooperation Treaty done at Washington, on June 19, 1970". See 35 U.S.C. § 351(a).

"The applicable time limit" referred to in the Patent Cooperation Treaty articles 22(1) a, 22(2) and 39(1)(a) is "the expiration of 30 months from the priority date." As a result "the expiration of 30 months from the priority date" is the time at which the U.S.

¹ Consistent with 37 C.F.R. § 1.702(b), MPEP §2730 states that "[i]n the case of an international application, the phrase "actual filing date of the application in the united States" [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stace commenced under 35 U.S.C. § 371(b) or (f).

national stage commences under the provisions of 35 U.S.C. § 371(b). This same conclusion as to the timing for commencement of the U.S. national stage is also summarized in MPEP § 1893.01.

In view of the foregoing, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for the purposes of calculating "B delay" under 37 C.F.R. § 1.702(b) and 35 U.S.C. 154(b)(1)(B), is the date that is 30 months from the priority date of the international application.²

The present application is a national stage filing under 35 U.S.C.§ 371 of International application number PCT/US04/20277, filed June 23, 2004, which claims the benefit of priority of US Patent application number 60/480,988 filed June 23, 2003.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), i.e., upon expiration of 30 months from the priority date of the international application. As a result the date that the national stage commenced was December 23, 2005.

The period beginning on December 24, 2008 (the day after the date that is three years after December 23, 2005) and ending July 10, 2010 (the date 4 months after payment of the issue fee) is **564 days** in length.

In contrast to reliance on "the expiration of 30 months from the priority date" for measuring "B delay", the beginning of the relevant period for purposes of calculating "A delay" is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II). and 37 C.F.R. § 1.702(a)(1).

March 10, 2010

Assuming that the patent will issue 4 months after payment of the issue fee, the effective period of adjustment under 37 C.F.R. § 1,702(b) is 564 days, i.e. from December 24, 2008 to July 10, 2010.

3. 37 C.F.R. § 1.702(c)-(e)

There are no relevant dates as specified under 37 C.F.R. §§ 1.703(a)-(e).

Calculation of Overlapping Days under 37 C.F.R. § 1,703(f) 4.

The A Delay accumulated during the following period: May 9, 2008 to April 30, 2009 and from November 30, 2009 to December 11, 2009. The "B delay" accumulated from December 24, 2008 to July 10, 2010. There are 139 days [128] days (December 24, 2008 - April 30, 2009) + 11 days (November 30, 2009 -December 11, 2009) in the overlapping periods under 37 C.F.R. § 1,703(a)-(e).

Applicants request that the overlapping periods be determined in accordance with Wyeth v. Kappos, Docket No. 2009-1120 (Fed. Cir. 2010). The periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B) overlap only if they occur on the same calendar day or days.

As discussed above. Applicants respectfully request an additional period of adjustment equal to the number of days, if any, under 37 C.F.R. § 1.703(a)(6).

Applicant delay 37 C.F.R. § 1.704

The correct period of adjustment under 37 C.F.R. § 1.704 is **345 days** ("Applicants delay"), not 0 days as indicated by the Patent Term Adjustment History (See Exhibit A).

- Response to Notice of DO/EO Missing Requirements mailed
 The correct period of adjustment under 37 C.F.R. 1.704(b) for the mailing of the

 Response to the Notice mailed on May 8, 2006 was 30 days, not 0 days as
- determined by the USPTO. The Response was marked as received on September 7, 2006 by the USPTO.
- Renewed Petition and Request for Reconsideration of Decision on Petition

The correct period of adjustment under 37 C.F.R. 1.704(c)(7) for the mailing of the Renewed Petition and Request for Reconsideration to the Decision on Petition mailed on November 9, 2006 was **183 days**, not 0 days as determined by the USPTO. The original Petition was received by the USPTO on September 7, 2006 and the Renewed Petition and Request was received by the USPTO on March 9, 2007.

 Supplemental Information Disclosure Statements filed November 3, 2009 and December 9, 2009 pursuant to 37 C.F.R. 1,704(c)(8).

The correct period of adjustment under 37 C.F.R. 1.704(c)(8) for the Supplemental Information Disclosure Statements filed on November 3, 2009 and December 9, 2009 is 132 days, not 0 days as determined by the USPTO. The last Supplemental Information Disclosure Statement was received by the Patent Office on December 9, 2009; 132 days after the receipt of the response to a Non-Final Office

Action on July 30, 2009. 37 C.F.R. § 1.703(f) indicates that to the extent that periods of delay attributable to the grounds specified in 37 C.F.R 1.702 overlap, the period of adjustment will not exceed the actual number of days the issuance of the patent was delayed. (M.P.E.P. § 2731).

The correct period of adjustment under 37 C.F.R. § 1.704 is **345 days** ("Applicants delay"), not 0 days as indicated by the Patent Term Adjustment History (See Exhibit A).

Terminal Disclaimer

This patent application is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Applicant believes that it is entitled to 447 days of patent term adjustment, i.e., [(A delay (367days) + B delay (564 days) – overlap (139 days)] – [Applicant delay (345 days)] under 37 C.F.R. § 1.703(f). Applicants are also entitled to any period of adjustment under 37 C.F.R. § 1.703(a)(6).

Should any additional fees be required for further consideration of the application and the enclosed information, the Commissioner is hereby authorized to charge such fees (or credit any overpayment) to Deposit Account 07-1139,

Appl. No. 10/562,374 March 10, 2010

referencing the docket number above.

Respectfully submitted,

Leslie Mooi

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March 10, 2010

Attachment: Exhibit A (2 pages)

367

10/562,374	COMPOSITIONS AND METHODS FOR INCREASING TELOMERASE ACTIVITY			03-08 2010::15(35:21
Patent Terr	n Adjustments			
Patent Term	Adjustment (PTA) f	for Application Num	ber: 10/562,374	
Filing or 371	(c) Date:	03-09-2007	USPTO Delay (PTO) Delay (days):	-
Issue Date of	f Patent:	-	Three Years:	-
Pre-Issue Petitions (days):		-	Applicant Delay (APPL) Delay (days)	: -

Total PTA (days):

Explanation Of Calculations

Post-Issue Petitions (days):

USPTO Adjustment(days):

Patent Term Adjustment History						
Date	Contents Description	PTO(Days)	APPL(Days)			
12-11-2009	Mail Notice of Allowance	11				
12-09-2009	Information Disclosure Statement (IDS) Filed	rije				
12-07-2009	Document Verification	ŵ				
12-07-2009	Notice of Allowance Data Verification Completed	ŵ				
12-07-2009	Case Docketed to Examiner in GAU	-1-				
12-01-2009	Examiner Interview Summary Record (PTOL - 413)	-fir				
12-02-2009	Examiner's Amendment Communication	4.74				
11-03-2009	Information Disclosure Statement considered	介				
07-30-2009	Information Disclosure Statement considered	11				
11-03-2009	Information Disclosure Statement (IDS) Filed	ήr				
03-11-2009	Reference capture on IDS	亦				
03-10-2009	Information Disclosure Statement (IDS) Filed	ŵ				
09-29-2009	Change in Power of Attorney (May Include Associate POA)	命				
03-13-2009	Information Disclosure Statement (IDS) Filed	小				
09-25-2009	Correspondence Address Change	49*				
07-30-2009	Information Disclosure Statement (IDS) Filed	양				
09-23-2009	Date Forwarded to Examiner	de				
07-30-2009	Response after Non-Final Action	ทัก				
09-18-2009	Change in Power of Attorney (May Include Associate POA)					
08-26-2009	Mail-Petition Decision - Granted					
08-26-2009	Petition Decision - Granted					
08-25-2009	Correspondence Address Change					
07-30-2009	Information Disclosure Statement (IDS) Filed					
06-25-2009	Petition Entered					
04-30-2009	Mail Non-Final Rejection	356				
04-27-2009	Non-Final Rejection	nh-				
03-11-2009	Information Disclosure Statement considered	金				
10-30-2008	Information Disclosure Statement considered	rit-				
03-13-2009	Information Disclosure Statement considered	1h				
03-13-2009	Information Disclosure Statement (IDS) Filed	ŵ				
03-11-2009	Information Disclosure Statement (IDS) Filed	ŵ				

10-30-2008	Reference capture on IDS	ŵ
10-30-2008	Information Disclosure Statement (IDS) Filed	曾
10-30-2008	Information Disclosure Statement (IDS) Filed	4
07-23-2008	Change in Power of Attorney (May Include Associate POA)	The state of the s
07-23-2008	Case Docketed to Examiner in GAU	分
07-23-2008	Correspondence Address Change	4
07-02-2008	IFW TSS Processing by Tech Center Complete	Tit*
07-23-2007	Miscellaneous Incoming Letter	4
05-15-2008	PG-Pub Issue Notification	ŵ.
02-19-2008	Application Dispatched from OIPE	rît-
03-09-2007	371 Completion Date	ŵ
02-11-2008	Sent to Classification Contractor	
02-11-2008	Notice of DO/EO Acceptance Mailed	
02-11-2008	Filing Receipt	
03-09-2007	A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in	
03-09-2007	CRF Disk Has Been Received by Preexam / Group / PCT	
03-09-2007	Additional Application Filing Fees	
03-09-2007	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	
07-23-2007	Mail-Petition Decision - Granted	
03-09-2007	Petition Entered	

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